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REMARKS

In the pending Office Action, Examiner Cumberledge rejected several of the pending claims as allegedly anticipated by the Assaker reference (U.S. Patent No. 5,620,444), and all of the claims as allegedly obvious over the Jackson reference (U.S. Patent No. 5,980,523) in combination with the Assaker reference. Respectfully, neither the Assaker reference by itself nor the combination of Jackson with Assaker show all elements of the claims. For that reason and others, the pending rejections should be withdrawn.

Turning first to the anticipation rejections, the Office Action asserted that the Assaker reference included all features of claims 1, 12-18 and 20-22. Although each of independent claims 1 and 13 are believed to define over the Assaker reference, to more clearly delineate the claimed subject matter the above-noted amendments have been made. Claims 1 and 13 recite a solid shaft and a second hook that includes a first end unitary with the shaft. The Assaker reference, particularly Figure 17 on which the Office Action's analysis relies, shows a non-solid item 25. Further, neither of the hooks in Figure 17 are unitary with item 25, but are separate parts capably of moving along it. On at least these grounds, claims 1 and 13 cannot be anticipated by the Assaker reference. It is also observed that, should possible obviousness be considered, the Assaker reference also cannot legitimately be modified to include a solid shaft and/or a unitary second hook, without going against the teachings relevant to Assaker's Figure 17 and fundamentally changing its operation.

Method claim 12 has been amended to include language that was inadvertently omitted from it and that is apparently needed in view of its reference to first and second hooks. Claim 12 was originally intended to include features of claim 1. With the now-explicit recitation of

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 8 of 17

subject matter from claim 1, the Assaker reference cannot anticipate or render obvious claim 12, for at least the reasons given above.

As another basis for withdrawing the anticipation rejection of claim 13, and also claim 22, Assaker does not show the second curve of the internal surface recited in those claims. The Office Action relies on surface or region 21 in Figure 10 as the recited "internal surface," but item 21 in Assaker does not curve in two directions. Assaker specifies that its item 21 is "defined . . . by a succession of rectilinear generatrices which generate a convex bearing surface" (column 5, lines 18-20). By being "rectilinear," these "generatrices" create a linear, part-cylindrical surface, as seen in Figures 10 and 11 of Assaker. In Figure 10 (reproduced below),

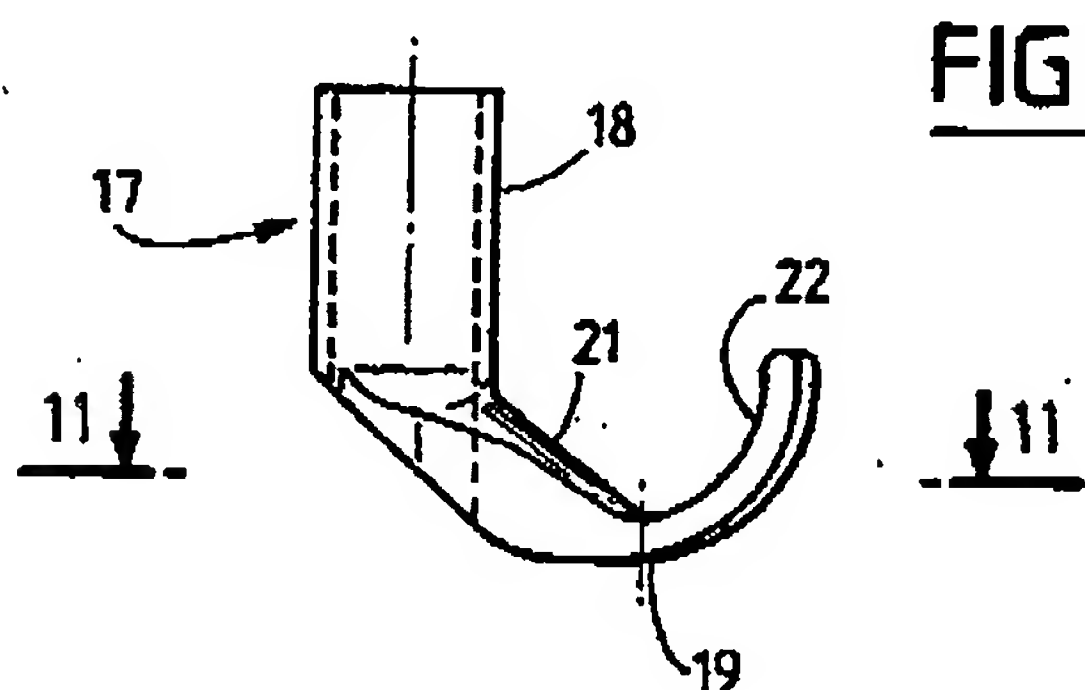


FIG. 10

item 21 is curved into and out of the page, but is linear in the plane of the page. The curve within the plane of the page, seen in item 22 of Figure 10, does not begin until item 21 ends. Thus, respectfully it cannot be said that there is a surface that curves in

two directions. For this additional reason, independent claims 13 and 22 are not anticipated by the Assaker reference.

Claim 14-18, 20 and 21 are dependent from claim 13, and are not anticipated by Assaker on at least the grounds noted above with respect to claim 13. Further, several of those claims define over the Assaker reference on their own merit. For example, claims 14-16 recite particular angular relationships between the curve directions, which relationships are not disclosed in Assaker. As to claim 17, which recites two spinal rods that lie non-parallel to each other, that subject matter is not shown in Assaker. The Office Action asserts only that since the

Assaker hook does not "completely encircle the rods, the rods can still be angled while they are being held in place by the hooks." No reference to the Assaker specification or drawings accompanies that statement, and nothing has been found in Assaker to support it. Assaker's Figure 17 clearly shows parallel rods, and its Figure 15 plainly suggests parallel rods. No showing of a proper basis for inherency has been made in the Office Action, and there is no indication that the Examiner is relying on personal knowledge. As to claim 18, the Office Action relies on Figure 15 of Assaker, claiming that the different lengths of the hooks in that drawing would cause rods to lie in different planes. Respectfully, however, that is not correct. The different hook lengths would in fact cause the rods to be in the same plane, but one that intersects with item 25 in Figure 15. See the rough representation of such a plane superimposed on Figure 15, below.

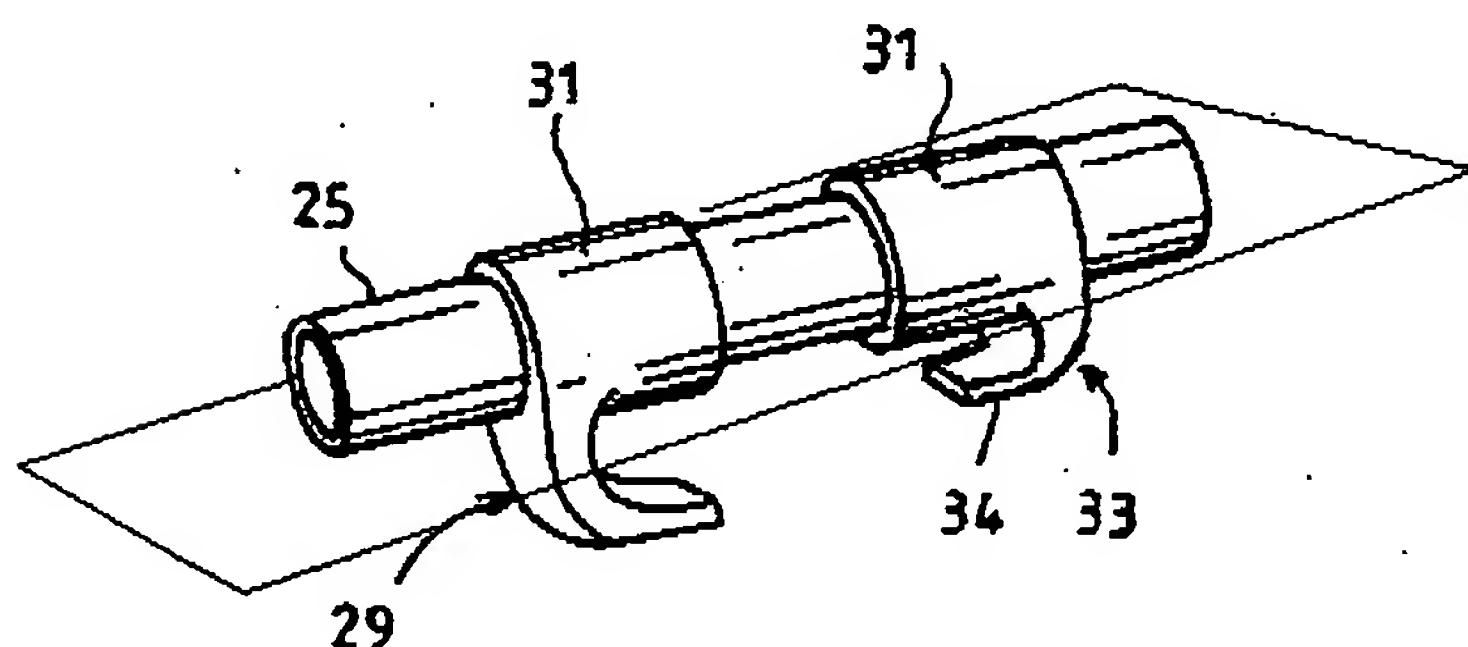


FIG. 15

If the hooks in Figure 15 were the same length, then that plane would be parallel to item 25. The configuration of Figure 15, consequently, does not cause the two rods to be outside of one plane. Claim 20 recites the claimed apparatus as a one-piece unit, which is not seen in Assaker or discussed in the Office Action. It is respectfully requested that the anticipation rejection of claims 14-18, 20 and 21 be withdrawn on these grounds as well.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 10 of 17

Turning now to the alleged obviousness rejections, it is respectfully requested that they be withdrawn because the Assaker and Jackson references cannot be combined as the Office Action proposes, and because even if combined, not all of the features of the claims are shown. For each of these reasons, further discussed below, a proper *prima facie* case of obviousness of the pending claims has not been established.

In this case, the motivation identified in the Office Action from the Assaker reference for combining the references would not have caused one of skill in this art to make a change in the Jackson reference, primarily because the asserted motivation is not a part of the use or operation of the Jackson reference. One of ordinary skill would not consider the Jackson structures to be useful in grasping vertebrae due to its structure and connection mechanisms. Jackson describes apparatus for linking two rods in the spaces between the spinous processes and transverse processes of the vertebrae, with the apparatus transversely connected to the rods. In that transverse direction, the Jackson apparatus cannot connect multiple vertebrae, and there is no suggestion in Jackson to turn it longitudinally to connect one vertebra to another. Moreover, the set screw connection mechanisms in Jackson plainly contradict any suggestion for using the device directly on bone. The Jackson device cannot be secured to another piece without the set screws that extend through the hook portions (see 22 and 73 in Fig. 5 of Jackson), which are designed to break at a predetermined torque (see, e.g. column 5, lines 1-3, column 8, lines 38-39 of Jackson). Use of any kind of set screws to secure the Jackson device directly to bone would cause damage to the bone by way of the pressing or crushing action of the set screw, generating additional pain, bone weakness or possibly worse conditions in the vertebra. However, using set screws designed to break at a given torque would force such damage to the bone. Such screws can only be used to anchor to relatively hard items, such as metal rods, as only then can the

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 11 of 17

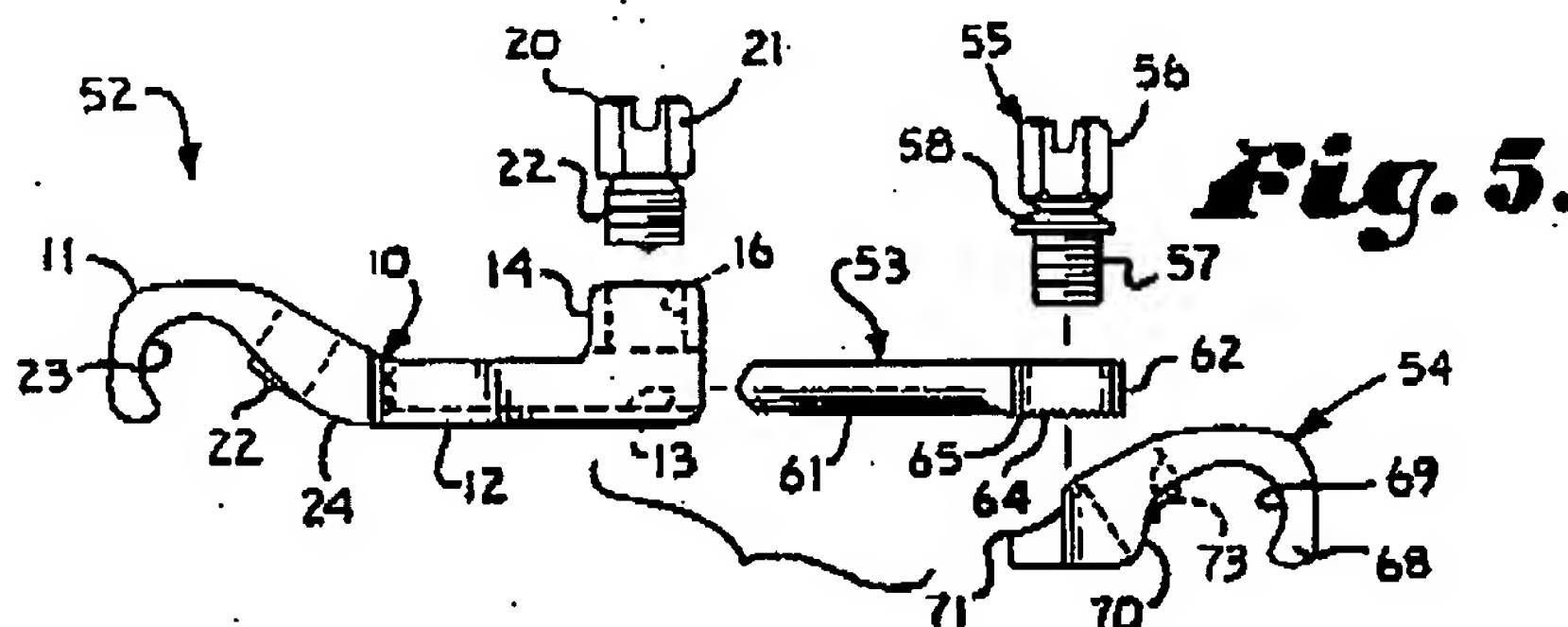
torque necessary for set screw breakage be reached. If such a set screw is tightened against the much softer bone, the bone material will be crushed or punctured without reaching that necessary torque.

Further, the Jackson reference specifically teaches that the "groove" 23 in its hooks is sized to receive rods, and that those rods fit "snugly and correctly into the associated groove 23 such that the radius of the groove 23 is perpendicular to the axis of the rod" when connected (column 4, lines 49-54). To have a radius of a groove ensured to be perpendicular to the rod axis, the groove must be substantially cylindrical, with a constant radius that is substantially the same as the rod. Adding item 21 of Assaker into groove 23 of Jackson foils the intended positioning of the rod in the groove. For this additional reason, Jackson teaches away from a non-cylindrical surface for mating with a rod, and the suggested combination is not warranted.

Consequently, if one of ordinary skill takes from the Assaker reference, as the Office Action suggests, that it teaches certain features for better connections directly to vertebrae, then that person would not associate that teaching with the Jackson apparatus, which cannot be used to link directly to bone. Conversely, if one of ordinary skill starts with Jackson's ideas of a transverse connector device for two longitudinal spinal rods, that person would understand that it cannot be used to link directly to vertebrae, and thus would not look to Assaker's structure to make putative improvements toward that non-use. One would also understand Jackson as teaching a cylindrical groove for a rod, and away from other configurations. Whether it is characterized as a conflict between the teachings of the references or of the reasonable inferences of the person of ordinary skill, the outcome is that the proposed motivation would not be taken by one of ordinary skill to be sufficient and indicate the desirability of modifying Jackson with Assaker as the Office Action suggests.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 12 of 17

Turning to the subject matter of the claims themselves, not all of the features in them are shown in the Jackson and Assaker references. Claim 1 recites a second hook having a second end spaced laterally from the shaft. If the alleged "second end" is considered to be adjacent number 23 in Jackson's Fig. 5 (reproduced below), it is clear that that end is not laterally spaced from the shaft, but is instead in line with the shaft. If the alleged "second end" is item 68 in Jackson's Fig. 5, it also is not laterally spaced from the shaft. As seen better in Jackson's Fig. 10, item 54 has a thin eyelet 71 on which item 62 connected to a shaft sits. End 68 is accordingly in line with item 53, not lateral from it.



Independent claims 12 and 13 also include a second end of a second hook that is laterally spaced from the shaft, while independent claim 22 similarly recites a hook with an end connected to a shaft and a second end spaced laterally from the shaft. Further, claims 1 and 13 recite that the second hood is unitary with the shaft, and as seen in Jackson's Fig. 5, neither its item 52 nor its item 54 is unitary with its item 53.

It should also be mentioned that it is not obvious to modify Jackson to make its items 52 and 53 unitary or its items 53 and 54 unitary, because doing so would go against Jackson's teachings and render the device unsatisfactory for its stated purposes. The degrees of freedom between items 52 and 53 and between items 53 and 54 are present to provide flexibility in connecting to imperfectly positioned rods. See, e.g., column 6, lines 23-28; column 2, line 50-

column 3, line 4 (especially column 2, lines 64-67). The separateness and moveability of the parts of the Jackson device are vital to its intended function, and thus one of ordinary skill could not infer from Jackson that it would be desirable to immovably join them from the start.

The remaining claims are dependent from the above-discussed independent claims, and are allowable because of that dependence. Many also include specific features that are not shown in either Assaker or Jackson. For example, claim 4 recites that the shaft defines a substantially planar plate. The Office Action's statement that item 10 in Figure 1 shows a plate-like shaft is incorrect, since item 10 is a "base connector" (see column 4, lines 40-41) as opposed to item 53 which is asserted in the figure in the Office Action to be the "shaft." Indeed, the Office Action's reproduction of Jackson's Figure 5 suggests that item 10 is an "interconnection element" in which a shaft is placed. Respectfully, the structure the Office Action relied on as a "shaft," item 53, is cylindrical, while there is no suggestion that any part of item 10 is a plate, or for that matter is anything but cylindrical.

Claim 5 recites that the shaft is curved, and the Office Action alleges that item 33 in Figure 1 is curved. Respectfully, Figure 1 shows a straight item 33, as does Figure 4. Moreover, if item 33 is curved, it would not be able to rotate around an axis with respect to "base connector" 10, as specified in column 5, lines 4-12. Accordingly, Jackson does not and cannot disclose a curved shaft.

Claim 6 recites a threaded aperture through the shaft and the curved portion of the first hook, and the Office Action suggests that item 73 of Jackson is such an aperture. However, as seen in Figure 5, item 73 does not go through any part of item 53, which the Office Action considers to be a "shaft." The only part that item 73 goes through is "neck or stem portion" 70

(column 6, lines 2-5). Claim 9 also recites a threaded aperture through the shaft, and thus also defines over Jackson.

Claims 10, 19, 20 and 27 recites the apparatus as a one-piece unit, and the Office Action simply relies on pre-Graham case law to say that making something in one piece involves only routine skill in the art. Respectfully, that analysis is not sufficient in this case, as already suggested. Even if the modification of Jackson is, in fact, within the capability of those of ordinary skill in this art, that fact alone is not enough to show obviousness. See MPEP 3143.01(IV). The scope and content of the Jackson reference clearly states that its device must be made from several pieces in order to perform the tasks for which it is intended. The reference itself establishes unequivocally the requirement that its device be in several mutually movable pieces, and no suggestion of any desirability of the opposite can be found in the reference. Thus, no *prima facie* case of obviousness can arise for claim 10 in the face of the clear teachings of the Jackson reference.

As to claims 14-16 and 21, as discussed above the Assaker reference does not show the subject matter of these claims. Since Jackson does not show any such internal surface configured as recited in these claims, the combination lacks these features as well.

As to claims 23 and 24, it is submitted that item 10 and item 14 of Jackson cannot reasonably be compared to the recited "interconnection element" and "stud," respectively. Moreover, claim 24 recites that the stud is received in an aperture, yet the Jackson reference does not show item 14 being received inside anything.

One final obviousness rejection was made, of claims 19 and 20 over the Assaker reference by itself, and again using pre-Graham case law for the proposition that a two-piece device made in one piece involves only "routine skill in the art." Just as discussed above with

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 15 of 17

respect to the Jackson reference, this ground is not sufficient to establish obviousness in this case because Assaker requires its parts to be separate in order to accomplish its goals. The Office Action relied on Figures 10, 15 and 17 in this case, and all of the structure therein is taught to be slidable with respect to another tube or hook portion for easy assembly and positioning (column 1, lines 63-67), and to be locked together by deforming the pieces (e.g. column 4, lines 14-40). Once again, the mere fact that a modification can be made, or that it would be within routine skill, is not enough for obviousness without some desirability of the modification. Here, where Assaker relies on the sliding of parts with respect to each other, it is impossible to discern any hint of desirability of making Assaker's devices in one piece.

These are examples of the dependent claims that are allowable on their own merit because neither Assaker nor Jackson show all of their features. Coupled with the fact that Jackson and Assaker cannot be combined as the Office Action proposes, the obviousness rejections of claims 1-28 should be withdrawn.

New claims 29 and 30 have been added. They are supported throughout the specification and drawings (including Figure 1 and associated text), and are dependent from claim 23, the allowability of which over the cited reference has been discussed above. No new matter has been added.

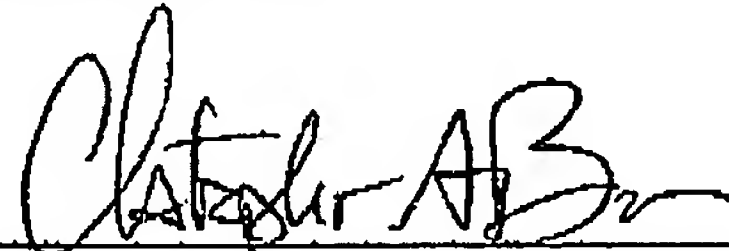
It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken by the examiner that are not specifically addressed herein.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 16 of 17

Reconsideration in view of the above remarks and a Notice of Allowance is respectfully requested. Should it be determined that any further action is necessary to place this application in better form for allowance, or for appeal should that become necessary, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/695,068
Atty. Dkt. No. 4002-3432
Page 17 of 17